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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,311	03/24/2006	Richard F. Ambinder	43369-103949	2676

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
06/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,311	AMBINDER ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 10-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-13 and 16-45 with the species of LMP-2 and GM-CSF in the reply filed on March 25, 2008 is acknowledged. The traversal is on the ground(s) that there is no extra burden to searching all of the claims in group II with group I since they have same limitations and same classification.

2. Applicants' argument has been fully considered; all of claims that are directed to the elected species are rejoined and considered. Therefore, claims 1-57 are pending. Claims 1-4, 10-57 in the species of LAM-2 and GM-CSF are considered. Claims 5-9 are withdrawn from consideration.

3. Because Applicants do not raise any question about the species election, the rest of requirement is still deemed proper and is therefore made FINAL.

4.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The invention of claims 1-4 and 10-13 are directed to non-statutory subject matter. There is no recitation of isolation or synthesis in front of the claimed human cell line. Therefore, the claimed compound read on naturally occurring materials, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language "isolated" to overcome this rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4 and 10-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having an isolated human erythroleukimia cell line K562, transfomed to co-express GM-CSF and EBV-LMP2 and using it to treat patients with Kaposi sarcoma or lymphoma, wherein the K562 cell line inherently lacks MHC-I and MHC-II, does not reasonably provide enablement for having any kind of cell lacking MHC-I and MHC-II to express any kind of immunogenic modulator with an EBV antigen had using it for treating any kind of cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

9. Claims 1-5, 10-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10. In the instant case, the claimed is directed to a genus of isolated human cell lines lacking MHC-I and MHC-II antigens expressions and genetically transformed to express any immunogenic modulator and an antigen of EBV. Another aspect of the claimed invention is also directed to a method using such human cell line to stimulate an immune response in a human with/without EBV associated cancer. Therefore, it appears from reading the specification that for a successful containing an isolated human cell line and a method for using said human cell line described above, the human cell lines are essential elements to practice the claimed invention. However, the specification does not provide a reproducible method to make such or point any direction to obtain such cell lines. Hence, it would require an undue experimentation to enable the invention. Therefore, for claims that need isolated human cell line, a deposit of such human cell line is required.

11. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be

irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

12. If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

a. during the pendency of this application, access to the deposits will be afforded to one determined by the commissioner to be entitled thereto;

b. all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c. the deposits will be maintained in the public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest;

d. a viability statement in accordance with the provisions of 37 CFR 1.807; and

e. the deposits will be replaced if they should become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

f. In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 16-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a K562 cell transformed with genes expressing GM-CSF and an EBV antigen and using this cell line to stimulate T cell expressing INFλ when it is administered into the patients having lymphoma and sarcoma, does not reasonably provide enablement for having a method using any human cell line lacking MHC-I and MHC-II gene expression and having an immune modulator and an EBV antigen expression to stimulate an immune response specifically against an EBV associated cancer for any human subject with/without a cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to male and use the invention commensurate in scope with these claims.

15. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following: 1). The nature of invention, 2). Scope of the claims, 3). State of art and Unpredictability of the field, 4). Working example presented in the specification; 5). Guidance provide in the specification; 6). Level of skill in the art, 7). Amount of the work to fulfill the scope of the claims.

16. The nature of the invention is directed to a transformed K562 cell line with genes encoding GM-CSF and an EBV antigen and a method for using this cell line to stimulating CD8 T cell response to said EBV antigen.

17. The state of art teaches that treatment of tumor has been tried by injecting autologous or allegeic cancer cells genetically manipulated for having GM-CSF expression into a cancer patient, wherein the allergenic cancer cell possible shears same tumor antigen of cancer patients, hereby an antigen specific T cell immune responses are produced. The state of art teaches that not all cytokine or immune modulators are benefit for the cancer treatment. Only GM-CSF is approved to stimulate the T cell immune response in (Draneff et al. 2002, Vol. 188, pp. 147-154). Moreover, there are so many immunologicl approaches using cancer vaccine to treat/prevent cancer being tried. However, even up today, some expertise in filed have concluded

that "numerous studies performed using sophisticated methods have convincingly demonstrated the possibility of induction of correct" antigen-specificity of induction of " " correct" antigen-specific cytolytic T lymphocytes and their infiltration to the tumor. As viral infections, a significant, if not major, portion of CD8+ T lymphocytes of patients had the required specificity, being able to kill tumor cells in vitro. Unfortunately, no clear reproducible clinical effects were observed in these studies ... It should also be mentioned that, although adoptive transfer of T cells after ex vivo manipulations proved to be applicable for tumor treatment, it will hardly be accessible for the majority of patients, even developed countries. Therefore, one cannot predict, now, whether this immunotherapeutic method will be able to supersede other modern cancer treatment methods." (Nedospasov et al. Molecular Biology 2007, Vol. 41, No. 2, pp. 316-328, especially, page 324).

18. The specification of the current Application teaches only K562 cell line transformed with gene encoding GM-CSF and an EBV antigen, and using cell line The K562 cell line to stimulate T cell activation in patients with the sarcoma and Lymphoma. No more examples has been taught in the specification that other cell line lacking MHC-I and MHC-II and transformed to express other immune modulator and an EBV antigen has been isolated and used for inducing an antigen specific immune response in cancer patients. Therefore. There is no sufficient evidence to support the broad scope of the scope of the claimed invention.

19. The level of the skill in art for cancer treatment is very high. Hence, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the full scope of the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Primary Examiner, Art Unit 1648